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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,089	10/04/2005	Joachim Hoernes	ROCHE-P003	4169
63049 7590 12/23/2010 BAKER & DANIELS LLP / ROCHE 300 NORTH MERIDIAN STREET SUITE 2700 INDIANAPOLIS, IN 46204				
EXAMINER				
OMCBA, ESSAMA				
ART UNIT		PAPER NUMBER		
3726				
NOTIFICATION DATE		DELIVERY MODE		
12/23/2010		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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### Office Action Summary

**Application No.**

10/552,089

**Applicant(s)**

HOENES ET AL.

**Examiner**

Essama Omgba

**Art Unit**

3726

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 December 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 2-25 and 28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-25 and 28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-940)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 12/6/2010
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on December 6, 2010 has been entered.

***Claim Rejections - 35 USC § 103***

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Claims 2-6, 8-19, 24, 25 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yuzhakov et al. (US 2002/0168290) in view of Kuhr et al. (US Patent 7,396,334).

With regards to claims 11, 18, 19 and 21-25, Yuzhakov et al. discloses a method for producing combined puncturing and measuring devices for detection of an analyte in liquid comprising a support 8 and a detection element 12 (see abstract and paragraph [0010]), the method comprising forming recesses (spaces between elements 212 in figure 6A) which define puncturing points 212 on one face of a band shape support material, applying a detection element 206, and separating individual

puncturing/measuring disposable bodies singly from the band-shaped support material at separating lines (fig. 6A and paragraph [0108]. Although Yuzhakov et al. does not explicitly disclose sealing the puncturing points by embedding each point in a soft plastic cover such that each surface of the puncturing points is in contact with the soft plastic cover, sterilizing the sealed puncturing points and the band-shaped support material such that the embedding of the puncturing points in the soft plastic cover provides for maintaining permanent pre-use sterility of the puncture points, and applying a detection element to the sterilized band-shaped support material, however such sealing, sterilizing and applying of a detection element is known as attested by Kuhr et al., see column 5, lines 8-19 and 47-49, column 8, lines 41-53 and 57-64 and column 9, lines 10-11. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made, to have sealed and sterilized the puncturing points and to have applied a detection element to the puncturing and measuring devices of Yuzhakov et al., in light of the teachings of Kuhr et al., in order to maintain sterility of the puncturing points prior to using them.

Regarding claim 2, see channel 238 and paragraphs [0104] , [0113] and [0114] of Yuzhakov et al.

Regarding claims 3-5, see figures 6A-6C of Yuzhakov et al.

Regarding claim 6, see channel 238 and paragraph [0082] of Yuzhakov et al.

Regarding claim 8, see paragraphs [0104] and [0112] of Yuzhakov et al.

Applicant should note that Yuzhakov et al. discloses that any known fabrication process may be used to manufacture the test strips.

Regarding claims 9 and 28, see figure 6A of Yuzhakov et al. Applicant should note that it is within the general skill level of a worker in the art to use a reel of band-shaped material in forming the puncturing and measuring devices.

Regarding claim 10, Applicant should note that it is conventional to ground such puncturing points, see for example column 5, lines 1-3 of Kuhr et al.

Regarding claims 12, 13 and 16, see paragraph [0116] of Yuzhakov et al. Applicant should note that applying different coatings one after the other or simultaneously is well known in the art of coextruding for example.

Regarding claims 14, 15 and 17, see figure 6A of Yuzhakov et al.

Regarding claim 20, applicant should note that the channels in the method of Yuzhakov et al. can be produced by embossing.

4. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yuzhakov et al./Kuhr et al. as applied to claim 2 above, and further in view of Ehrlich (US Patent 2,801,633).

Yuzhakov et al./Kuhr et al. discloses a method for producing combined puncturing and measuring devices as shown above. Although Yuzhakov et al./Kuhr et al. does not specifically show the depressions having a depression base with a triangular contour, however it is known to form such depressions with depression bases having triangular, round or oval contour as attested by Ehrlich, see figures 8 and 9. Therefore it would have been obvious to have formed the depressions of the device of Yuzhakov et al./Kuhr et al. with a depression base having a triangular contour, in light of the teachings of Ehrlich, as a matter of obvious design choice.

***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Essama Omgba whose telephone number is (571) 272-4532. The examiner can normally be reached on M-F 9-6:30, 1st Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Bryant can be reached on (571) 272-4526. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Essama Omgba/  
Primary Examiner, Art Unit 3726